

April 8, 2004

INFORMATION DISCLOSURE  
STATEMENT  
Patent Application  
Docket No. GJE-44D1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Robert Graham Feldman, Gordon Dougan, Joseph David Santangelo, David  
William Holden, Jacqueline Elizabeth Shea, Zoe Hindle  
Docket No. : GJE-44D1  
For : Attenuated Microorganisms for the Treatment of Infection

Mail Stop PATENT APPLICATION  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §§1.97 and 1.98, Applicants would like to bring to the attention of the Examiner, the references cited in the following patent application:

U.S. Serial No. 09/569,601, filed May 9, 2000.

The subject application claims the benefit under 35 USC §120 of the filing date of patent application Serial No. 09/569,601. Applicants respectfully request that the copies of references supplied in the Information Disclosure Statement of the 09/569,601 application, as well as any references cited during the prosecution thereof, be made of record in the subject application. As copies of the references made of record in the 09/569,601 application, and cited on the attached form PTO/SB/08, can be found in the 09/569,601 casefile, copies of those references are not provided herewith.

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

Applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statements.

Respectfully submitted,



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DRP/mdp  
Attachment: Form PTO/SB/08

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number		
			Filing Date		
			First Named Inventor		
			Art Unit		
			Examiner Name		
Sheet	1	of	3	Attorney Docket Number	
				GJE-44D1	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	U1	US-5,876,931	03-02-1999	Holden	All
	U2	US-5,643,579	07-01-1997	Hung <i>et al.</i>	All
	U3	US-			
	U4	US-			
	U5	US-			
	U6	US-			
	U7	US-			
	U8	US-			
	U9	US-			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	F1	EPO 0889120 B1	01-07-1999	Microscience Limited	All	
	F2	WO 00/14240	03-16-2000	CREATOGEN BIOSCIENCES GMBH	All	
	F3					
	F4					
	F5					
	F6					
	F7					

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	
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Sheet	2	of	3
		Attorney Docket Number	
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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R1	MEDINA, E. <i>et al.</i> "Pathogenicity Island 2 Mutants of <i>Salmonella typhimurium</i> Are Efficient Carriers for Heterologous Antigens and Enable Modulation of Immune Responses", <i>Infection and Immunity</i> , 1999, pp. 1093-1099, Vol. 67, No. 3.	
	R2	VALENTINE, P.J. <i>et al.</i> "Identification of Three Highly Attenuated <i>Salmonella typhimurium</i> Mutants That Are More Immunogenic and Protective in Mice than a Prototypical <i>aroA</i> Mutant", <i>Infection and Immunity</i> , 1998, pp. 3378-3383, Vol. 66, No. 7.	
	R3	HENSEL, M. <i>et al.</i> "Genes Encoding Putative Effector Proteins of the Type III Secretion System of <i>Salmonella</i> Pathogenicity Island 2 are Required for Bacterial Virulence and Proliferation in Macrophages", <i>Molecular Microbiology</i> , 1998, pp. 163-174, Vol. 30, No. 1.	
	R4	HENSEL, M. <i>et al.</i> "Analysis of the Boundaries of <i>Salmonella</i> Pathogenicity Island 2 and the Corresponding Chromosomal Region of <i>Escherichia coli</i> K-12", <i>Journal of Bacteriology</i> , 1997, pp. 1105-1111, Vol. 179, No. 4.	
	R5	HENSEL, M. <i>et al.</i> "Functional Analysis of <i>ssaJ</i> and <i>ssaK/U</i> Operon, 13 Genes Encoding Components of the Type III Secretion Apparatus of <i>Salmonella</i> Pathogenicity Island 2", <i>Molecular Microbiology</i> , 1997, pp. 155-167, Vol. 24, No. 1.	
	R6	SHEA, J.E. <i>et al.</i> "Influence of the <i>Salmonella typhimurium</i> Pathogenicity Island 2 Type III Secretion System on Bacterial Growth in the Mouse", <i>Infection and Immunity</i> , 1999, pp. 213-219, Vol. 67, No. 1.	
	R7	SHEA, J.E. <i>et al.</i> "Identification of a Virulence Locus Encoding a Second Type III Secretion System in <i>Salmonella typhimurium</i> ", <i>Proc. Natl. Acad. Sci. USA</i> , 1996, pp. 2593-2597, Vol. 93.	
	R8	CHATFIELD, S. N. <i>et al.</i> "Construction of a Genetically Defined <i>Salmonella typhi</i> Ty2 <i>aroA</i> , <i>aroC</i> Mutant for the Engineering of a Candidate Oral Typhoid-Tetanus Vaccine", <i>Vaccine</i> , 1992, pp. 53-60, Vol. 10, No. 1.	
	R9	LEVINE, M.M. <i>et al.</i> "Attenuated <i>Salmonella</i> as Live Oral Vaccines Against Typhoid Fever and as Live Vectors", <i>Journal of Biotechnology</i> , 1996, pp. 193-196, Vol. 44, No. 1-3.	
	R10	DOUGAN, G. <i>et al.</i> "Live Bacterial Vaccines and Their Application as Carriers for Foreign Antigens", <i>Advances in Veterinary Science and Comparative Medicine</i> , 1989, pp. 277-300, Vol. 33.	
	R11	HOHMANN, E.L. <i>et al.</i> "Evaluation of a <i>phoP</i> / <i>phoQ</i> -deleted, <i>aroA</i> -deleted Live Oral <i>Salmonella typhi</i> Vaccine Strain in Human Volunteers", <i>Vaccine</i> , 1996, pp. 19-24, Vol. 14, No. 1.	
	R12	LOWE, D.C. <i>et al.</i> "Characterization of Candidate Live Oral <i>Salmonella typhi</i> Vaccine Strains Harboring Defined Mutations in <i>aroA</i> , <i>aroC</i> , and <i>htrA</i> ", <i>Infection and Immunity</i> , 1999, pp. 700-707, Vol. 67, No. 2.	
	R13	SCHODEL, F. <i>et al.</i> "Hepatitis B Virus Nucleocapsid/pre-S2 Fusion Proteins Expressed in Attenuated <i>Salmonella</i> for Oral Vaccination", <i>Journal of Immunology</i> , 1990, pp. 4317-4321, Vol. 145, No. 12.	

Examiner Signature		Date Considered	
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STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

Application Number	
Filing Date	April 8, 2004
First Named Inventor	Robert Graham Feldman
Group Art Unit	
Examiner Name	
Attorney Docket Number	GJE-44D1

Sheet	3	of	3
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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R14	PLOTKIN, S. A. <u>Vaccines</u> , 1988, p. 571, W.B Saunders Co., Philadelphia.	
	R15		
	R16		
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